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10/762,133

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Stephen D. Russell

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OFFICE OF PATENT COUNSEL
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EXAMINER

BAXTER, ZOE E

ART UNIT

PAPER NUMBER

3735

DATE MAILED: 12/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/762,133	Applicant(s) RUSSELL ET AL.	
	Examiner Zoe E. Baxter	Art Unit 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 17-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 12, 13, 15 and 16 is/are rejected.
- 7) ☒ Claim(s) 11 and 14 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>1/20/2004</u> . | 6) <input type="checkbox"/> Other: ____. |

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-16, drawn to a micro-sensor, classified in class 600, subclass 345.
 - II. Claims 17-20, drawn to a micro-sensor array system, classified in class 600, subclass 345.
 - III. Claim 21-27, drawn to a method of fabricating a micro-sensor probe, classified in class 438, subclass 001.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct if they do not overlap in scope and are not obvious variants, and if it is shown that at least one subcombination is separately usable. In the instant case, subcombination II has separate utility such as a physiological sensor. See MPEP § 806.05(d).
3. The examiner has required restriction between subcombinations usable together. Where applicant elects a subcombination and claims thereto are subsequently found allowable, any claim(s) depending from or otherwise requiring all the limitations of the allowable subcombination will be examined for patentability in accordance with 37 CFR 1.104. See MPEP § 821.04(a). Applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

4. Inventions I and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product can be made by another and materially different process.

5. Inventions II and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product can be made by another and materially different process.

6. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

7. During a telephone conversation with Allan Lee on November 1, 2006 a provisional election was made without traverse to prosecute the invention of a micro-sensor, claims 1-16. Affirmation of this election must be made by applicant in replying to this Office action. Claims 17-27 withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

DETAILED ACTION

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1, 8 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Koning et al. (US Patent No. 4716887). Koning et al. teach a probe comprising a housing having an aperture, an ISFET attaches to the housing (column 8 lines 3-15) wherein the ISFET has a gate located proximate the aperture and a reference electrode attached to the housing proximate to the aperture (column 8 lines 28-34).

10. Referring to claim 8 Koning et al. teach a CO₂ permeable membrane formed across and sealing the opening of the probe forming a sealed chamber which defines an exterior space in which a portion of the gate and reference electrode are in fluid communication with the exterior space (column 8 lines 10-15).

11. Referring to claim 12 Koning et al. teach a microsensor system comprising a control module (column 5 lines 28-36), a probe comprising: a housing having an aperture, an ISFET attaches to the housing (column 8 lines 3-15) wherein the ISFET has a gate located proximate the aperture and a reference electrode attached to the housing proximate to the aperture (column 8 lines 28-34).

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 2 and 3 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as being inherent over Koning et al. It is inherent that the housing and the ISFET are integrally formed in biocompatible material. The ISFET has to be secured some how to the catheter otherwise it would not stay in line with the aperture and both have to be made of a biocompatible material so as not to produce an adverse reaction upon insertion into the body.

14. Referring to claim 3 it is inherent that the housing and the reference electrode be integrally formed in biocompatible material. Again the reference electrode cannot be free to move about the catheter and both need to be formed in a biocompatible material so as not to produce an adverse reaction upon insertion into the body.

15. Claims 2, 3 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koning et al. in view of Ishikawa et al. (US Patent No. 6447448). Koning et al. teach a probe comprising a housing having an aperture, an ISFET attaches to the housing (column 8 lines 3-15) wherein the ISFET has a gate located proximate the aperture and a reference electrode attached to the housing proximate to the aperture (column 8 lines 28-34). Koning et al. fail to clearly define that the housing and the

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ISFET are integrally formed in biocompatible material. Ishikawa et al. teach a housing and an ISFET integrally formed (column 8 lines 22-39) and teach that the entire sensor should be coated with a biocompatible material (column 9 lines 1-5). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify a the probe of Koning et al. to include a biocompatible coating since as Ishikawa et al point out it is a common practice in the art and since the sensor is in contact with the body it needs to be biocompatible so as not to cause harm.

16. Referring to claim 3 Koning et al. teach a teach a probe comprising a housing having an aperture, an ISFET attaches to the housing (column 8 lines 3-15) wherein the ISFET has a gate located proximate the aperture and a reference electrode attached to the housing proximate to the aperture (column 8 lines 28-34). Koning et al. fail to clearly define that the housing and the reference electrode are integrally formed in biocompatible material. Ishikawa et al. (US Patent No. 6447448) teach a housing and a reference electrode integrally formed (column 8 lines 22-39) and teach that the entire sensor should be coated with a biocompatible material (column 9 lines 1-5). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify a the probe of Koning et al. to include a biocompatible coating since as Ishikawa et al point out it is a common practice in the art and since the sensor is in contact with the body it needs to be biocompatible so as not to cause harm.

17. Referring to claim 10 Koning et al teach microsensor system comprising: a probe comprising: a housing having an aperture, an ISFET attached to the housing (column 8 lines 3-15) wherein the ISFET has a gate located proximate the aperture and a

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reference electrode attached to the housing proximate to the aperture (column 8 lines 28-34). Koning et al. fail to teach an antenna and capacitor system in which the antenna is coupled to the capacitor and the capacitor is coupled to the ISFET where in the capacitor is configured to store electromagnetic energy received by the antenna. Ishikawa et al. teach an antenna and capacitor system in which the antenna is coupled to the capacitor and the capacitor is coupled to the ISFET where in the capacitor is configured to store electromagnetic energy received by the antenna (column 13 lines 33-53). It would be obvious to one of ordinary skill in the art at the time of the invention to modify the invention of Koning et al to include the antenna system similar to that of Ishikawa et al. in order to create a system in which no battery is required.

18. Claims 4 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koning et al. in view of Abreu (PGPUB 2002/0049389). Koning et al. teach a probe comprising a housing having an aperture, an ISFET attaches to the housing (column 8 lines 3-15) wherein the ISFET has a gate located proximate the aperture and a reference electrode attached to the housing proximate to the aperture (column 8 lines 28-34) and the gate and a portion of the reference electrode are located within the aperture (column 8 lines 28-34). Koning et al. fail to teach the housing is a hermetically sealed encapsulant. Abreu teaches a sensor, which comprises an ISFET and a housing, which is a hermetically sealed encapsulant (page 15 paragraph 0153). Since both sensors use the same ISFET technology and are used in wet locations, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify

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the invention of Koning et al. to include a hermetically sealed encapsulant similar to that of Abreu in order to prevent fluid invasion causing problems in the electronics.

19. Referring to claim 9 Koning et al. teach a probe comprising a housing having an aperture, an ISFET attaches to the housing (column 8 lines 3-15) wherein the ISFET has a gate located proximate the aperture and a reference electrode attached to the housing proximate to the aperture (column 8 lines 28-34) and the gate and a portion of the reference electrode are located within the aperture (column 8 lines 28-34). Koning et al. fail to teach an electrical power generator. Abreu teaches the use of a battery coupled to the ISFET (page 15 paragraph 0158). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the invention of Koning et al. to include a battery similar to that of Abreu in order to provide a power source.

20. Claims 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koning et al. in view of Tomita et al. (U.S. Patent No. 5814280). Koning et al teach microsensor system comprising: a probe comprising: a housing having an aperture, an ISFET attached to the housing (column 8 lines 3-15) wherein the ISFET has a gate located proximate the aperture and a reference electrode attached to the housing proximate to the aperture (column 8 lines 28-34). Koning et al. fail to teach a substrate wherein the ISFET and reference electrode are integrally formed on the substrate, wherein the ISFET and reference electrode are monolithically integrated and wherein the ISFET and the microelectrode are located on a portion of the substrate that includes the aperture. Tomita et al. teach a substrate including an ISFET and a reference electrode above the ISFET (column 4 lines 29-45). It is obvious to have the

combination located on a portion of the substrate that includes the aperture in order to introduce the substance being measured to the ISFET to be able to measure the amount of the substance. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the invention of Koning et al. to include a substrate similar to that of Tomita et al. in order to make the unit more economical to manufacture (Tomita et al. column 4 lines 52-60).

21. Referring to claim 6 Tomita et al. further teach that associated circuitry can be integrated with the ISFET and the reference electrode (column 4 lines 45-51). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the invention of Koning et al. to integrate the associated circuitry similar to that of Tomita et al. in order to make the unit more economical to manufacture.

22. Referring to claim 7 Tomita et al. further teach the integrated circuitry includes a temperature sensing diode (column 4 lines 36-37). It would have been obvious to one of ordinary skill in the art at the time of the invention to include a temperature sensing diode similar to that of Tomita et al in order to compensate for drift related to temperature change (Tomita et al. column 4 lines 37-39).

23. Claims 13 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koning et al. in view of Cliffel et al. (PGPUB US 2005/0014129) Koning et al teach microsensor system comprising: a probe comprising: a housing having an aperture, an ISFET attached to the housing (column 8 lines 3-15) wherein the ISFET has a gate located proximate the aperture and a reference electrode attached to the housing proximate to the aperture (column 8 lines 28-34). Koning et al. fail to teach a system

comprising an actuator. Cliffel et al. teach a system comprising an ISFET and an actuator (page 10 paragraph 0186). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the invention of Koning et al. to include an actuator similar to that of Cliffel et al. in order to produce a feedback system as stated by Cliffel et al. (page 10 paragraph 0187).

24. Referring to claim 15 Koning et al teach microsensor system comprising: a probe comprising: a housing having an aperture, an ISFET attached to the housing (column 8 lines 3-15) wherein the ISFET has a gate located proximate the aperture and a reference electrode attached to the housing proximate to the aperture (column 8 lines 28-34). Koning et al. fail to teach a system comprising a piezoelectric actuator. Cliffel et al. teach a system comprising an ISFET and a piezoelectric actuator (page 17 paragraph 0231). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the invention of Koning et al. to include an actuator similar to that of Cliffel et al. in order to simply control the size of the opening in which the sensor is fixed.

25. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Koning et al. in view of Nakamura et al. (US Patent No. 4736748). Koning et al teach microsensor system comprising: a probe comprising: a housing having an aperture, an ISFET attached to the housing (column 8 lines 3-15) wherein the ISFET has a gate located proximate the aperture and a reference electrode attached to the housing proximate to the aperture (column 8 lines 28-34). Koning et al. fail to teach a system comprising an electromagnetic actuator. Nakamura et al. teach an electromagnetic

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actuator in combination with an ISFET (column 28 lines 50-56). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the invention of Koning et al. to include an electromagnetic in order to produce a feedback system.

Allowable Subject Matter

26. Claims 11 and 14 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

27. Referring to claim 11 prior art of record fail to teach or fairly suggest a microprobe comprising a calibrant in contact with the gate of an ISFET and a reference electrode.

28. Referring to claim 14 prior art of record fail to teach or fairly suggest a microsensor with a cantilever arm attached to the actuator.

Conclusion


29. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zoe E. Baxter whose telephone number is 571-272-8964. The examiner can normally be reached on Monday-Friday 7:30am-4:00pm.

30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571-272-4730. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

31. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Charles A. Marmor, II
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Art Unit 3735

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